

REMARKS

Reconsideration of this application is requested. Claims 15-22 are active in the application subsequent to entry of this Amendment.

The claims have been revised and assembled into a single claim set and two new claims, 17 and 22, have been added. The Official Action indicates that claims 12-14 are objected to as depending from a rejected claim but are otherwise allowable. Claims 12-14 correspond substantially with new claims 19-21, so these claims are deemed to be allowable and are not further discussed in this response. Claims 15, 16 and 18 correspond substantially to previous claims 9-11 and these three claims were the subject of a "obviousness" rejection over two U.S. patents by DeMichele U.S. 6,013,665 and its continuation application 6,160,007. As the second is a continuation of the first the content of them is substantially identical.

Basis in the original disclosure for new claim 17 is discussed in the remarks that follow. New independent claim 22 is a combination of the above claims 1, 17 and 18.

The sole issue raised in the outstanding Official Action is the rejection of previous claims 9-11 (see new claims 15, 16 and 18) as being "obvious" over the disclosures of two references. Before responding to the examiner's comments and observations and argument in support of the rejection, it is appropriate to again review the legal standards required to establish a *prima facie* case of obviousness.

The obviousness or unobviousness of the claims in question is to be determined following the analysis set forth in *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). The analysis requires determining the scope and content of the prior art, ascertaining the differences between the prior art and the claims in issue, resolving the level of ordinary skill in the pertinent art, and lastly evaluating evidence of secondary considerations of patentability.

In the first, instance the examiner must present a *prima facie* case of obviousness. In order to do so, the art cited must include the following elements: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

"Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Clay*, 966 F.2d 656, 658-9, 23 U.S.P.Q. 2d 1058, 1060 (Fed. Cir. 1992).

The question is whether DeMichele describes information which is reasonably pertinent to the particular problem with which the present inventors were involved.

"A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering this problem." *In re Clay*, 966 F.2d at 659, 23 U.S.P.Q. 2d at 1061.

It is applicants' position that the subject matter of the applied references, which relates to a method for enhancing the absorption of oil soluble compounds such as oil soluble vitamins, hormones, nutrients and drugs, is a substantially different field of endeavor than that of the present application, namely to provide an oil or fat composition which is less accumulated as body fat while maintaining excellent cooking properties, flavor, and the like. Counsel appreciates that applicants are pursuing composition claims. When reviewing these claims it is important to remember that the *components of the composition are selected* with the particular objective in mind, thus the objectives set out in the applied references are not at all the same as the objectives of the present invention. One having ordinary skill in the art focussing on the problem to which the present invention is directed, namely providing an oil or fat composition which is less accumulated as body fat certainly has different objectives in mind than a person

investigating methods for enhancing absorption of oil soluble compounds in an animal. Care must be taken in reviewing the content of the prior art to view it from the viewpoint of one having ordinary skill in the art interested in providing an oil or fat composition which is less accumulated as body fat and also be reminded that the references are concerned with methods for enhancing absorption of oil soluble compounds in an animal. Thus the teachings and descriptions of the references are not directly transferable to the intent and claims of the present invention, and vice versa.

In the Official Action claims 9-11 are rejected under 35 U.S.C. 103 (a) as being unpatentable over DeMichele (6,160,007 or 6,013,665). Applicants disagree with this rejection for at least the following reasons.

The characteristic elements of the present invention are:

- ① the proportion of medium-chain fatty acids to all the fatty acids constituting the oil or fat composition is 5 to 23 % by mass,
- ② the proportion of triglycerides having two medium-chain fatty acid residues in the molecule to all the triglycerides is 1 to 20 % by mass, and
- ③ the proportion of long-chain saturated fatty acids to all the long-chain fatty acids constituting the oil or fat composition is 20 % by mass or less.

Applicants have included a subclaim further restricting the requisite of the above ③. This preferred value is disclosed at page 6, line 31 of the substituted specification, thus claim 17 finds basis in the original disclosure.

The cited prior art is now discussed with reference to the essential elements of the claimed compositions.

About requisite ①:

When examination of DeMichele U.S. Patent No. 6,160,007 (the description of U.S. Patent No. 6,013,665 is almost the same as that of U.S. Patent No. 6,160,007) is made in contrast to the above requisite of ①, the ratio of medium-chain fatty acids : long-chain fatty acids ranging from about 1:3 to about 3:1 is described in Column 9 of DeMichele, as pointed out by the Examiner. The ratio of medium-chain fatty acids : long-chain fatty acids = 1:3 to 3:1 means that in the expression of the above ①, the proportion

of medium-chain fatty acids to all the fatty acids constituting the oil or fat composition of DeMichele (=structured triglyceride) is 25 to 75 % by mass. This value is clearly out of the 5-23% range of ①. Further, since in DeMichele, medium-chain fatty acids : long-chain fatty acids = 1:2 to 2:1 is typical, and this means that DeMichele recommends 33.3 to 67.7 % by mass as the proportion of medium-chain fatty acids to all the fatty acids constituting the structured triglyceride, and, therefore, this teaching of DeMichele makes the structured triglyceride of DeMichele further remote from the above requisite of ①. The reason why 33.3 to 67.7 % by mass is recommended is, probably, that the proportion is suitable for accomplishing the objectives/results of DeMichele of enhancing the absorption of oil soluble (lipophilic) compounds in animals (Abstract) of DeMichele.

Based on the given "variation in ratios of medium and long chain fatty acids and the predicted impact of the ratio on the overall composition"¹ (Action, page 2, line 7 from the bottom), the Examiner agrees that it could have been apparent to the skilled person to select the above range of ①. Column 9 of DeMichele does not show what is varied and how it is varied not in composition but in properties, by varying the ratio of medium-chain fatty acids: long-chain fatty acids between 1:3 to 3:1 as apparently asserted in the Action. What is shown is instead that 33.3 to 67.7 % by mass, further apart from the above range of ①, is preferred as the ratio of medium-chain fatty acids to all the fatty acids.

The above requisite ① in combination with the above requisite ② brings about an unexpected result of being low in body fat accumulation (the present specification, page 17, lines 17 to 28), but such result (or object) is not disclosed nor suggested in DeMichele at all. Instead, DeMichele is concerned with enhancing absorption of oil soluble compounds such as vitamins.

Even if an oil or fat composition having the proportion of medium-chain fatty acids to all the fatty acids constituting the oil or fat composition of 25 to 75 % by mass had been suggested to one skilled in the art, he couldn't have reached the above requisite

①, without having any objective intention to do so. In other words, the one skilled in the art couldn't have expected that varying the proportion of medium-chain fatty acids to all the fatty acids constituting the oil or fat composition leads to reduction in body fat accumulation. Moreover, according to the above preferred numerical range of DeMichele, the one skilled in the art would have been led in a direction further afield from the above requisite ①.

Although the Action offers the conjecture "[g]iven the variation in ratios of medium and long chain fatty acids and the predicted impact of the ratio on the overall composition, one of ordinary skill in the art could modify the starting materials of DeMichele in order to achieve the desired oil composition of the claims", this conclusion is not based upon the contention of the applied reference but on supposition and hindsight reconstruction of the art. The object of the present claims (reducing body fat accumulation) must have been unclear to a person skilled in the art at the priority date of the present application. The object (effect) of the present invention is also part of the present invention, and not technical background.

The Examiner also refers to Table 2 of DeMichele. Although this reference seems to relate to the above requisite of ③, a structured triglyceride of DeMichele is exemplified in Table 2. For the sake of completion of the record, applicants comment if this structured triglyceride meets the above requisite of ①. The proportion of medium-chain fatty acids to all the fatty acids constituting the structured triglyceride is 47.5% by mass more than twice the upper limit of the above requisite of ①. Since this exemplified structured triglyceride is considered as representing a best mode, one skilled in the art will be led in a direction further afield from the present invention by this teaching of DeMichele.

The mere fact the references can be modified or combined is not enough. As stated by the Court in *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783-1784 (Fed. Cir. 1992)(emphasis added):

¹ Although it is not entirely clear, counsel assumes "predicted impact" in this phrase means affect

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.

Thus, the mere fact that references can be combined or modified (Applicants believe they cannot be) does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 U.S.P.Q.2d 1430 (Fed.Cir. 1990); MPEP § 2143.01.

The Action is silent regarding the above requisite of ②. Since an invention must be considered as a whole, some disclosure of this required feature is necessary to prove obviousness of all the requisites for establishing a *prima facie* case of obviousness.

In order to establish obviousness it is necessary to demonstrate that ~~each element~~ of the claimed subject matter may be found or is reasonably suggested by the prior art. In the present situation the record does not establish that the applied references pertain at all to feature ② given above, that is the proportion of triglycerides having two medium-chain fatty acid residues in the molecule relative to all the triglycerides. Having failed to establish this essential feature of the present invention, the rejection must fall.

About requisite ③

The Examiner states about this feature “At Table 2 the level of saturated fat in the fish oil is shown to be at less than 10 %”, but what is meant by “saturated fat” is unclear and in any event counsel is unable to find description of less than 10% in Table 2.

What applicants are able to glean from Table 2 is that the proportion of long-chain saturated fatty acids to all the long-chain fatty acids in the structured triglyceride is $(2.9+4.7+0.6)/(2.9+4.7+0.6+4.1+5.7+0.8+1.5+1.0+1.5+15.1+1.8+8.0+4.3) \times 100 = 15.8\%$ by mass (“others” was considered as long-chain unsaturated fatty acids). Therefore, the structured triglyceride meets the above requisite of ③. However, since the present invention must be examined on obviousness as a whole, and the above requisites of ① and ② are not suggested, the patentability of the present claims cannot be denied. In any

on the final composition.

event, applicants have included new claim 17 in which the long-chain saturated fatty acids are at most 15 % by mass of all the long-chain fatty acids as constituents of the oil or fat composition.

When this proportion is more than 20 % by mass, stability at low temperatures is lowered and crystallization of oil or fat occurs in the oil or fat composition (the present specification, page 7, lines 8-16). The object of stability at low temperatures is not disclosed nor suggested in DeMichele. Therefore, although the above requisite of ③ happens to be met in a composition exemplified in DeMichele, one skilled in the art would have no objective intention to think of setting the proportion of long-chain saturated fatty acids to all the long-chain fatty acids constituting the oil or fat composition at 15-% by mass or less for imparting stability at low temperatures. Namely, claim 17 is unobvious over DeMichele on the basis of all three characterizing features.

Claim 18 requires a further feature, namely ④ the proportion of triglycerides having three medium-chain fatty acid residues in the molecule to all the triglycerides constituting the oil or fat composition is 3% by mass or less.

The Action includes nothing about this requisite. Claim 18 is patentable on the basis of requisites ①, ② and ④.

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See Dembiczak, 175 F.3d at 999, 50 U.S.P.Q.2d at 1617. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983)). Applicants submit the rejection is based largely or entirely on hindsight and not what the references actually teach the art.

Most if not all inventions arise from a combination of old elements. *See In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Thus, every

element of a claimed invention may often be found in the prior art. *See id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *See In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998).. Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *See B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp.*, 72 F.3d 1577, 1582, 37 U.S.P.Q.2d 1314, 1318 (Fed. Cir. 1996). The record of this application demonstrates no motivation to modify the teachings of the DeMichele references, thus a prima facie case of obviousness has not been established.

Reconsideration and allowance are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100